MEDI-CAL UPDATE Part 2
Billing and Policy
www.medi-cal.ca.gov

Outpatient Services • Clinics and Hospitals

December 2005 • Bulletin 374

Contents

Date of Service Determines Correct Modifier for Billing

Providers are reminded that the recently implemented national modifiers are to be used only for dates of service on or after the effective date noted in *Medi-Cal Updates.* For the following types of service, providers should use the appropriate modifiers for the date of service billed.

Type of Service	Interim (Old) Modifiers	National (Current) Modifiers	Bill National Modifier for Dates of Service On or After
Telemedicine	TM	GT	August 1, 2005
Anesthesia Complicated by Hypothermia	AG	ET, P5	August 1, 2005
Emergency Anesthesia	AF	P4	August 1, 2005
Hearing Aids, Accessories and Services	Y1, Y2, Y6, Y7	NU, RR, RP	November 1, 2005
2005 Modifier Conversion	YQ, YS, ZK, ZU, ZV	22, AG, SA, SB, SC	November 1, 2005

For more in-depth details, see the June 2005 and September 2005 *Medi-Cal Update* for your specific provider community.

The updated information is reflected on manual replacement pages modif app 4 thru 7 (Part 2).

2006 CPT-4/HCPCS Code Update Reminder

The 2006 updates to the *Current Procedural Terminology*, Fourth Edition, (CPT-4) and Healthcare Common Procedure Coding System (HCPCS) Level II codes become effective for Medicare on January 1, 2006. The Medi-Cal program has not yet adopted the 2006 updates. Do not use 2006 codes to bill for Medi-Cal services until notified to do so in a future *Medi-Cal Update*.

Provider Restrictions for O & P Reimbursement

Providers are reminded that effective for dates of services on or after October 1, 2003, only physicians, podiatrists, certified orthotists and prosthetists may be reimbursed for orthotic and prosthetic appliances. Codes with double asterisks (**) in the *Orthotic and Prosthetic Appliances: Billing Codes and Reimbursement Rates — Orthotics* section of the provider manual are also reimbursable to pharmacists.

TdaP Vaccine is New VFC Benefit

TdaP (tetanus, diphtheria toxoids and acellular pertussis) vaccine is a new benefit for the Vaccines For Children (VFC) program. Medi-Cal reimburses VFC providers an administrative fee for providing the TdaP injection. TdaP is for use in individuals 11 through 18 years of age. For an interim period, this drug will be billed with CPT-4 code 90749 (unlisted vaccine/toxoid) and modifier -SL (VFC-supplied vaccine) retroactive to dates of service on or after September 15, 2005.

When billing code 90749, providers must document in the *Remarks* area, or on an attachment to the claim, that code 90749 was used to bill the VFC administrative fee for TdaP.

At this time TdaP is not a Medi-Cal benefit but will be reviewed for consideration as a benefit in the future.

A special timeliness override has been developed in the claims processing system for TdaP claims submitted with code 90749.

Note: Retain this Article
Because code 90749 is being used to bill TdaP for a short time only, billing instructions are not being added to the provider manual. This article constitutes the official billing instructions for using code 90749 when billing TdaP and should, therefore, be retained by providers.

Looking Ahead
In 2006, unlisted code 90749 will be discontinued for billing the TdaP administration fee, and this service will then be billed with CPT-4 code 90715 (tetanus, diphtheria toxoids and acellular pertussis vaccine [TdaP], for use in individuals seven years of age or older, for intramuscular use). Modifier -SL must still be used. Additional information and manual pages concerning code 90715 will be released in a future *Medi-Cal Update*.

VFC Reminder that DECAVAC is Billed with New Code Starting January

Last month's *Medi-Cal Update* announced that the administration fee for DECAVAC is a new benefit for the Vaccines For Children (VFC) program. The article indicated that the code to use for billing DECAVAC would change in January 2006. The following chart summarizes the two codes and corresponding dates of service to use for billing DECAVAC.

Dates of Service	Bill With	CPT-4 Description
On January 1, 2005 through December 31, 2005	CPT-4 code 90749 and modifier -SL (state supplied vaccine)	Unlisted vaccine/toxoid
On or after January 1, 2006	CPT-4 code 90714 and modifier -SL	Diphtheria and tetanus toxoids [Td] adsorbed, preservative free, for use in individuals seven years of age or older, for intramuscular use

Code 90714
Code 90714 is not listed in the 2005 *Current Procedural Terminology – 4th Edition* (CPT-4) code book. This is a 2006 CPT-4 code that the CPT Editorial Panel released early to report the most recent new or revised vaccine product codes.

Code 90714 is not a Medi-Cal benefit. The comparable Medi-Cal benefit is CPT-4 code 90718 (diphtheria and tetanus toxoids [Td] adsorbed for use in individuals seven years of age or older, for intramuscular use).

Please see **DECAVAC**, *page 3*

DECAVAC *(continued)*

Code 90749 Reminders
Providers were instructed that when billing for code 90749, they must document in the *Remarks* area or on an attachment to the claim, that code 90749 was used to bill the VFC administrative fee for DECAVAC. This documentation is not a requirement for code 90714.

Claims submitted with code 90749 for dates of service on or after January 1, 2005 through December 31, 2005 are excluded from the six-month billing limit.

Code 90714 information is reflected on manual replacement page vaccine 3 (Part 2).

Laboratory Procedures Benefit Update

Effective for dates of service on or after January 2, 2006, the following HCPCS Level II laboratory procedure codes are Medi-Cal benefits:

HCPCS Code	Description
Q0111	Wet mounts, including preparations of vaginal, cervical or skin specimens
Q0112	All potassium hydroxide (KOH) preparations
Q0113	Pinworm examinations

These codes must be billed with modifier -ZS. Providers billing these codes must meet Clinical Laboratory Improvement Amendment (CLIA) requirements.

This information is reflected on manual replacement pages hcpcs ii 2 (Part 2) and path micro 2 (Part 2).

Coding Update for Blood Clotting Factor Disorder Products

Effective for dates of service on or after September 1, 2005, Medi-Cal will reimburse the following blood derivative anti-hemophilia codes:

HCPCS Code	Description	Max U/V/S
J7197	Antithrombin III (human) per IU	01
J7198	Anti-inhibitor, per IU	01
Q0187	Factor VIIa per 1.2mg	01
Q2022	Von Willebrand factor (complex) per IU	01

The following HCPCS codes may also be billed using product trade names as the descriptors: J7197 includes “Thrombate III, Atnativ”; J7198 includes “Autoplex T, Feiba VH Immuno”; and code Q0187 may be called “NovoSeven.” All of these codes must be billed “By Report” with the appropriate HCPCS code and a copy of the invoice attached to the claim.

Factor VIIa (HCPCS code Q0187) was previously billed with HCPCS code Z5230. Effective for dates of service on or after September 1, 2005, HCPCS Z5230 may not be used to bill Factor VIIa.

Antithrombin III (human) was previously billed with HCPCS code Z5204 and reimbursed at acquisition cost plus. For dates of service on or after September 1, 2005, providers must bill Antithrombin III (human) with HCPCS code J7197, which will be reimbursed at the Average Selling Price (ASP) plus 20 percent.

This information is reflected on manual replacement pages blood 1 and 2 (Part 2), blood ub 3 thru 6 (Part 2) and cal child ser 15 and 16 (Part 2).

Newborn Screening Panel Rate Increase

Effective retroactively to dates of service on or after January 1, 2005, the reimbursement rate for a newborn screening panel (HCPCS code Z2500) increased to $78. The increase includes a request form fee of $1 required by the Genetic Disease Department.

All claims paid for dates of service on or after January 1, 2005 at the lower rate will be reprocessed automatically.

This information is reflected on manual replacement pages gene ex 3 (Part 2), rates max 7 (Part 2) and rates max lab 8 (Part 2).

Delalutin Reimbursable with ICD-9 Code V23.41

Effective for dates of service on or after January 1, 2006, HCPCS code X5974 (17 hydroxyprogesterone caproate [Delalutin], 250 mg/ml 5cc) is reimbursable when billed in conjunction with ICD-9 diagnosis code V23.41 (pregnancy with history of pre-term labor). Medi-Cal will reimburse the injection once every seven days between 16 and 36 weeks gestation.

The updated information is reflected on manual replacement page preg early 4 (Part 2).

HCPCS Codes Z1208 and Z1210 Terminated

Effective for dates of service on or after January 1, 2006, interim HCPCS codes Z1208 (minilaparotomy for female sterilization) and Z1210 (transection of fallopian tube unilateral/bilateral with mini-lap, postpartum) are terminated.

Providers should bill these services using CPT-4 codes 58600 (ligation or transection of fallopian tube[s], abdominal or vaginal approach, unilateral or bilateral) and 58605 (ligation or transection of fallopian tube[s], abdominal or vaginal approach, postpartum, unilateral or bilateral, during the same hospitalization [separate procedure]), which are currently Medi-Cal benefits.

The updated information is reflected on manual replacement pages fam planning 10 (Part 2), medi non hcp 3 (Part 2), rates max 4 (Part 2) and ster 22 (Part 2).

Diagnostic Radiology Policy Update

Effective for dates of service on or after January 2, 2006, interim HCPCS codes X0700 (portable X-ray, two patients) and X0702 (portable X-ray, three or more patients) will no longer be reimbursable. Providers should use national HCPCS codes R0070 (transportation of portable X-ray equipment and personnel to home or nursing home, per trip to facility or location; one patient seen) or R0075 (…more than one patient seen, per patient) when billing for portable X-ray services. In addition, HCPCS code Q0092 (set-up portable X-ray equipment) will also be reimbursable. None of the above codes may be split-billed.

Portable X-ray service providers may only bill R0070 and R0075 for the same recipient a second time on the same date of service if justification is documented in the *Remarks* area of the claim, or on an attachment, indicating the reason for a second visit.

Claims for HCPCS codes Q0092, R0070 and R0075 will be automatically reprocessed for payment, retroactive to dates of service on or after August 20, 2005. Reimbursement rates for HCPCS codes R0070 and R0075 were increased.

Please see **Radiology**, *page 5*

Radiology *(continued)*

For dates of service on or after August 20, 2005, HCPCS code R0075 must be billed with an appropriate modifier and is priced "By Report" incrementally up to and no greater than $174.06 (the rate of R0070). Providers must bill one of the following national modifiers in conjunction with HCPCS code R0075 in order for the claim to be reimbursed:

Modifier	Description
-UN	Two patients served
-UP	Three patients served
-UQ	Four patients served
-UR	Five patients served
-US	Six or more patients served

This information is reflected on manual replacement pages hcpcs ii 2 (Part 2), hcpcs iii 4 (Part 2), medi pro med 1 (Part 2), modif app 4 (Part 2) and radi dia 22 (Part 2).

Bevacizumab (Avastin) is New Benefit to Treat Colorectal Cancer

Effective for dates of service on or after January 1, 2006, bevacizumab (Avastin), 100 mg (HCPCS code S0116) is reimbursable solely for the treatment of metastatic colorectal cancer. Bevacizumab is reimbursable in connection with ICD-9 diagnosis codes 153.0 – 154.8 (malignant neoplasm of the colon, rectum, rectosigmoid junction and anus). Providers must document in the *Remarks* area of the claim that bevacizumab is being billed to treat metastatic colorectal cancer.

This information is reflected on manual replacement pages chemo 31 (Part 2) and inject list 3 (Part 2).

Palonosetron: New Benefit

Effective for dates of service on or after November 1, 2005, palonosetron (Aloxi) 25 mcg (HCPCS code J2469) is reimbursable for acute and delayed emesis due to emetogenic chemotherapy. Palonosetron may be combined with aprepitant and dexamethasone for maximal patient benefit for both acute and delayed emesis due to highly emetogenic chemotherapy.

Dosage
A single intravenous dose of 0.25 mg delivered over 30 seconds is given 30 minutes before chemotherapy. Palonosetron may be billed in conjunction with CPT-4 code 96408 (chemotherapy administration, intravenous; push technique).

This information is reflected on manual replacement pages chemo 28 (Part 2) and inject list 14 (Part 2).

Cancer Detection Programs: Every Woman Counts Online Claims Approved Based on Recipient Eligibility Period

The online application system for the Cancer Detection Programs: Every Woman Counts was set up to approve claims based on a recipient's eligibility period rather than the date the service was provided. Claim forms submitted outside the recipient's eligibility period will generate a denial message stating that the recipient's information was incomplete (*Remittance Advice Details* [RAD] code 9576).

Providers are reminded to submit their claims within the eligibility period for each program recipient to avoid receiving this denial.

For more information, call the Telephone Service Center (TSC) at 1-800-541-5555.

Frequency Restriction for Cardiac Implantable Devices

Effective for dates of service on or after January 2, 2006, cardiac implantable devices and stents have a frequency restriction of once a year for the same recipient by the same provider. Medical justification documented in the *Remarks* area is required for any surgical implantable device claims billed more than once a year.

This information is reflected on manual replacement page surg cardio 7 (Part 2).

Surgical Implantable Devices Policy Clarification

As a clarification, since implantable devices are considered surgical supplies, they are only reimbursable if the surgical procedure is performed on the same recipient for the same date of service. The claim for the implantable device may be on a separate claim from the claim for the surgical procedure.

This information is reflected on manual replacement page surg 5 (Part 2).

Once-in-a-Lifetime Procedures Update

Effective for dates of service on or after January 1, 2006, the following services are Medi-Cal reimbursable only once in a recipient's lifetime. Claims submitted for these procedures a second time for the same recipient must include a full explanation and medical justification to avoid being denied.

CPT-4 Code	Description
58262	Vaginal hysterectomy, for uterus 250 grams or less; with removal of tube(s), and or ovary(s)
58263	Vaginal hysterectomy, for uterus 250 grams or less; with removal of tube(s), and or ovary(s), with repair of enterocele
58550	Laparoscopy surgical, with vaginal hysterectomy, for uterus 250 grams or less
58954	Bilateral salpingo-oophorectomy with omentectomy, total abdominal hysterectomy and radical dissection for debulking with pelvic lymphadenectomy and limited para-aortic lymphadenectomy
58956	Bilateral salpingo-oophorectomy with total omentectomy, total abdominal hysterectomy for malignancy

This information is reflected on manual replacement page once 3 (Part 2).

Prenatal Cystic Fibrosis Screening Policy Clarification

To clarify current Medi-Cal billing policy on cystic fibrosis screening procedures, providers are reminded that CPT-4 codes 83890, 83891, 83892, 83893, 83894, 83896, 83897, 83898, 83901, 83904 and 83912 are used to bill for molecular diagnostic techniques for various clinical purposes. Additionally, the following billing policy applies for these codes:

- When used to bill for the purpose of cystic fibrosis screening tests, providers must also use ICD-9 code V26.3, which must be documented in the *Principle Diagnosis Code* field (Box 67) of the claim.
- When used to bill for tests other than cystic fibrosis screening, the claims must be billed with valid ICD-9 codes other than V26.3.

The updated information is reflected on manual replacement pages path molec 1 and 2 (Part 2).

New CCS Service Code Grouping 09 for Chronic Dialysis Clinics

Chronic Dialysis Clinics are identified with unique Service Code Grouping (SCG) 09 to facilitate the diagnosis and treatment of California Children's Services (CCS) clients, effective retroactively for dates of service on or after July 1, 2004. SCGs allow providers to submit a single code on a Service Authorization Request (SAR) that represents a wide range of services. If the SAR is approved, all codes in the Service Code Grouping identified on the SAR are reimbursable.

The updated information is reflected on manual replacement page cal child ser 22 (Part 2).

CCS Service Code Groupings Update

A number of codes have been added and deleted from the Service Code Grouping (SCG) tables for the California Children's Service (CCS) program. In addition, for provider convenience each added or deleted code is accompanied by a symbol that relates directly to each code's effective date. Codes with a † have an effective date of October 18, 2004, while codes with a †† have an effective date of November 1, 2005. Codes without a symbol are effective July 1, 2004. Codes marked for deletion also have a line through each code.

The updated information is reflected on manual replacement pages cal child ser 1, 3 thru 17 and 20 (Part 2).

Presumptive Eligibility Change of Address

Effective immediately, the address for the Presumptive Eligibility (PE) section has changed. Please send all PE forms to the new address:

Department of Health Services
Presumptive Eligibility Support Unit
MS 4607
P.O. Box 997417
Sacramento, CA 95899-7417

The updated information is reflected on manual replacement pages presum 10, 12, 15 and 21 (Part 2).

Human Papillomavirus DNA or RNA Test Restrictions Update

This is a clarification to an article published in the October 2005 Medi-Cal Update. Effective for dates of service on or after November 15, 2005, new reimbursement requirements were initiated for Human Papillomavirus (HPV) test code 87621 (infectious agent detection by nucleic acid [DNA or RNA]; papillomavirus, human, amplified probe technique).

Family PACT and Medi-Cal providers must bill CPT-4 code 97621 with one of the ICD-9 codes below. Only Family PACT providers must bill CPT-4 code 87621 with a primary diagnosis "S" code in addition to one of the below ICD-9 codes. Claims for dates of service on or after November 15, 2005 for CPT-4 code 87621 that were billed by Family PACT providers without the primary "S" diagnosis code and were denied for an incorrect diagnosis code will need to be resubmitted by those providers with an appropriate primary diagnosis "S" code as well as one of the ICD-9 codes below in order to be reimbursed.

HPV test codes 87620 (infectious agent detection by nucleic acid [DNA or RNA]; papillomavirus, human, direct probe technique) and 87622 (…papillomavirus, human, quantification) referenced in the October 2005 *Medi-Cal Update* were deleted previously from the Family PACT program effective for dates of service on or after April 30, 2004 (April 2004 *Medi-Cal Update*).

Please see **HPV**, *page 8*

HPV *(continued)*

Reimbursement of HPV screening is supported for women who qualify to receive the following services:

- Reflex testing for high-risk types of HPV in women with an ASC-US Pap smear, as an alternative to repeat cervical cytology or colposcopy, when a liquid-based cytology collection method has been used.
- Follow-up of Low-grade Squamous Intraepithelial (LSIL) cytology result in women less than 21 years of age (HPV DNA testing at 12 months in lieu of cytology at six and 12 months is an option).
- Follow-up post colposcopy in women with Paps read as Atypical Squamous Cell, High Grade (ASC-H), LSIL, or HPV DNA positive Atypical Squamous Cells of Undetermined Significance (ASC-US) in whom Cervical Intraepithelial Neoplasia (CIN) is not identified at colposcopy (may be followed up at 12 months with HPV DNA testing in lieu of cytology at six and 12 months).
- Follow-up of women with biopsy proven CIN I (HPV DNA testing at 12 months in lieu of cytology at six and 12 months is an option).
- Follow-up in women post treatment of CIN II and III (HPV DNA testing at least six months after treatment in lieu of three follow-up Pap smears is an option).

Code 87621 may be billed with modifier -26, - TC or -ZS and is reimbursable once every 12 months, any provider, for female recipients 15 years of age or older when billed concurrently with one of the following ICD-9 codes:

ICD-9 Code	Description
233.1	Carcinoma in situ of breast and genitourinary system; cervix uteri
622.11	Dysplasia of cervix (uteri); mild dysplasia of cervix
622.12	Dysplasia of cervix (uteri); moderate dysplasia of cervix
795.01	Papanicolaou smear of cervix with atypical squamous cells of undetermined significance (ASC-US)
795.02.1	Papanicolaou smear of cervix with atypical squamous cells cannot exclude high grade squamous intraepithelial lesion (ASC-H)
795.03	Papanicolaou smear of cervix with low grade squamous intraepithelial lesion (LGSIL)
795.05	Cervical high risk human papillomavirus (HPV) DNA test positive

The revised *Family PACT Policies, Procedures and Billing Instructions* (PPBI) manual will be issued in a future *Updated Information.*

This information is reflected on manual replacement page path micro 3 (Part 2).

New Sterilization Consent Form for Family PACT Providers Coming Soon

Begin using the PM 330 now for sterilizations scheduled on or after February 1, 2006.

Effective for dates of service on or after February 1, 2006, claims submitted by Family PACT providers for elective sterilizations (CPT-4 codes 55250, 58600, 58615, 58670, 58671, 00851 or 00921) must adhere to all Medi-Cal policies described in the *Sterilization* section of the Part 2 provider manual, including submission of a Department of Health Services sterilization *Consent Form* (PM 330). Use of the PM 330 also includes the following policy updates:

- Recipients must be a minimum of 21 years of age.
- A minimum 30-day waiting period between the recipient's consent and the date of the sterilization procedure is required.

Claims for elective sterilization from Family PACT providers for dates of service prior to February 1, 2006 must continue to follow current Family PACT policy as applied to the sterilization *Consent Form* (PM 284).

The revised *Family PACT Policies, Procedures and Billing Instructions* (PPBI) will be issued in a future *Updated Information*. For more information regarding Family PACT, call the Telephone Service Center (TSC) at 1-800-541-5555.

Provider Orientation and Update Sessions

Medi-Cal providers seeking enrollment in the Family PACT (Planning, Access, Care and Treatment) Program are required to attend a Provider Orientation and Update Session. The dates for the first quarter of 2006 are listed below.

Group providers wishing to enroll must send a physician-owner to the session. Clinics wishing to enroll must send the medical director or clinician responsible for oversight of medical services rendered in connection with the Medi-Cal provider number.

Office staff members, such as clinic managers and receptionists, are encouraged to attend but are not eligible to receive a *Certificate of Attendance*. Currently enrolled clinicians and staff are encouraged to attend to remain current with program policies and services. Medi-Cal laboratory and pharmacy providers are automatically eligible to participate in the Family PACT Program without attending an orientation session.

The session covers Family PACT provider enrollment and responsibilities, client eligibility and enrollment, special scope of client services and benefits, provider resources and client education materials. This is not a billing seminar.

Please note the upcoming Provider Orientation and Update Sessions below.

January 23, 2006
Department of Health Services Auditorium
1500 Capitol Avenue
Sacramento, CA 95814

March 20, 2006
Department of Health Services Auditorium
1500 Capitol Avenue
Sacramento, CA 95814

For a map and directions to the DHS Auditorium, go to the Family PACT Web site at **www.familypact.org** and click "map" under "Orientation Sessions."

Registration
To register for an Orientation and Update session, go to the Family PACT Web site at **www.familypact.org,** click the appropriate date under "Orientation Sessions" and print out a copy of the registration form. Fill out the form and fax it to the Office of Family Planning at (916) 650-0468.

Please see **Family PACT**, *page 10*

Family PACT *(continued)*

If you do not have Internet access, you may request the registration form by calling 1-877-FAMPACT (1-877-326-7228). Providers must supply the following:

- Name of the Medi-Cal provider or facility
- Medi-Cal provider number
- Contact telephone number
- Anticipated number of people attending

Check-In
Check-in begins at 8 a.m. All orientation sessions start promptly at 8:30 a.m. and end by 4:30 p.m. At the session, providers must present the following:

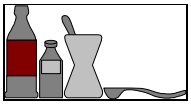
- Medi-Cal provider number
- Medical license number
- Photo identification

Note: Individuals representing a clinic or physician group should use the clinic or group Medi-Cal provider number, not an individual provider number or license number.

Certificate of Attendance
Upon completion of the orientation session, each prospective new Family PACT medical provider is mailed a *Certificate of Attendance*. Providers should include the original copy of the *Certificate of Attendance* when submitting the Family PACT application and agreement forms (available at the session) to Provider Enrollment Services. Providers arriving late or leaving early will not be mailed a *Certificate of Attendance*. Currently enrolled Family PACT providers do not receive a certificate.

Contact Information
For more information regarding the Family PACT Program, please call 1-877-FAMPACT or visit the Family PACT Web site at **www.familypact.org**.

The Family PACT Program was established in January 1997 to expand access to comprehensive family planning services for low-income California residents.



DRUG USE REVIEW
Educational Information

FDA Warnings of Suicidal Behavior in Children Taking Antidepressants or Atomoxetine

In September 2005, the Food and Drug Administration (FDA) released a public health advisory warning (similar to the warning released in 2004 regarding all antidepressant medications) of suicidal thinking and behavior in children and adolescents. This article summarizes the clinical trial data and information released by the FDA on atomoxetine and antidepressants, and provides utilization data on the use of these agents in the Medi-Cal pediatric population.

I. Suicidality with Atomoxetine

The FDA and its Pediatric Advisory Committee recently requested an analysis of adverse event data from Eli Lilly's atomoxetine database and clinical trials. The FDA's request for this review was prompted by prior findings that antidepressants pose an increased risk of suicidal thoughts and behavior in children taking them. The analysis of atomoxetine data identified a statistically significant increased risk of suicidal thoughts among atomoxetine-treated children and adolescents as compared to placebo groups (4 per 1,000 patients in the atomoxetine group compared to none in the placebo group). There was one suicide attempt observed in among a total of 2,200 patients, and this patient was in the atomoxetine-treated group.

On September 29, 2005, the FDA issued a Public Health Advisory to alert patients and medical professionals of reports of suicidal thinking in children and adolescents taking atomoxetine. The FDA directed Eli Lilly to add a "boxed" warning on the labeling, and to create a medication guide for pharmacists to distribute with all new and refill prescriptions of atomoxetine for children/adolescents.

Please see **FDA Warnings**, *page 11*

FDA Warnings *(continued)*

The FDA advised that upon starting treatment with atomoxetine or changing dose of the drug, pediatric patients must be closely monitored for a few months for the advent of the following signs/symptoms:

- Clinical worsening
- Unusual changes in behavior
- Agitation, irritability
- Suicidal thinking or behavior

It is not yet known if the suicidality in children/adolescents is a phenomenon that extends to the traditional ADHD medications. In early 2006, the FDA plans to complete an ongoing review of side effect data for all ADHD medications.

II. In 2004 the FDA Issued a Black Box Warning Regarding Suicidality in Children and Adolescents with All Antidepressants

On September 16, 2004, the FDA released the following recommendations made by the Psychopharmacologic Drugs and Pediatric Advisory Committees:

- Concluded that increased risk of suicidality in pediatric patients applied to all the drugs studied (fluoxetine, sertraline, mirtazapine, paroxetine, venlafaxine, citalopram, bupropion, fluvoxamine, nefazodone) in controlled clinical trials
- Recommended that warnings of increased risk of suicidality in pediatric patients be applied to all antidepressant drugs
- Recommended a "black-box" warning and endorsed a Medication Guide with every prescription for this class of drugs
- Recommended that the products not be contraindicated because access to these therapies are important

On October 15, 2004, the FDA announced its decision to require a "Black Box Warning and Medication Guide" for the use of all antidepressants in children and adolescents under 18 years of age. New warning language did not prohibit the use of antidepressants in children and adolescents. It only warned of the risk of suicidality and encouraged providers to balance this risk versus benefit. The approved medication guide can be obtained at **www.fda.gov/cder/drug/antidepressants/MG_template.pdf**.

III. How Are Medi-Cal Providers Impacted?

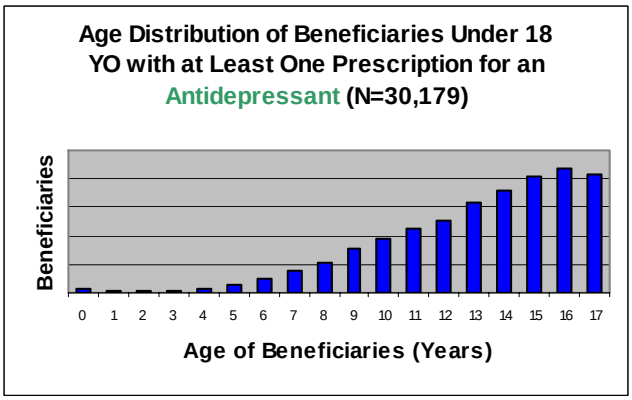
The FDA has issued two warnings to alert medical professionals of reports of suicidal thinking and behavior in children and adolescents taking antidepressants and atomoxetine. Between September 2004 and September 2005, a large number of Medi-Cal recipients were being treated with these agents. Therefore, it is important to properly counsel and closely monitor all pediatric patients who are starting new therapy with these agents, those who are titrating dosage and those with a predisposition/history of bipolar disorder.

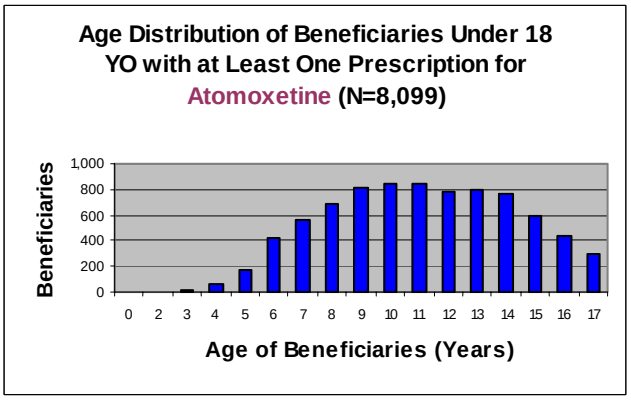
Medi-Cal is actively monitoring the impact that the label changes have made to antidepressants and atomoxetine on the utilization of these drugs and clinical outcomes.

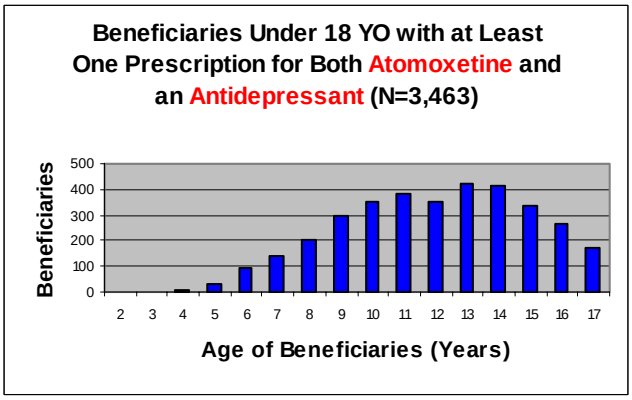
To report any unexpected adverse events associated with these agents, contact the FDA MedWatch program at 1-800-FDA-1088; by fax at 1-800-FDA-0178; by mail to MedWatch; Food and Drug Administration; HFD-410; 5600 Fishers Lane; Rockville, MD 20857-9787; or online at **www.fda.gov/medwatch/report.htm**.

Please see **FDA Warnings**, *page 12*

FDA Warnings *(continued)*







Please refer to pages 36-26 and 27 in the Medi-Cal Drug Use Review Manual.

Instructions for Manual Replacement Pages — Part 2

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Remove and replace:	blood 1/2
	blood ub 3 thru 6
	cal child ser 1 thru 22
Remove:	chemo 27 thru 30
Insert:	chemo 27 thru 32 *(new)*

Remove and replace:	cont ip 1 thru 4 *
	fam planning 9/10
	gene ex 3
	hcpcs ii 1/2
	hcpcs iii 3/4
	inject list 3/4, 13/14
	medi non hcp 1/2 *, 3
	medi pro med 1
	medne 5/6 *
	modif app 1 thru 7
	once 3/4
	oth hlth cpt 1/2 *
	path micro 1 thru 4
	path molec 1/2
	preg early 3/4
	presum 9 thru 12, 15/16, 21
	radi dia 21/22
	rates max 3/4, 7/8
	rates max lab 7/8
	respir 3/4 *
	ster 21/22
	surg 5
	surg cardio 7
	ub sub 1/2 *
	vaccine 3/4

DRUG USE REVIEW (DUR) MANUAL

Remove from the *Education* section:	36-25
Insert:	36-25 thru 27 *(new)*

* Pages updated due to ongoing provider manual revisions.